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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,441

11/10/2003

Gerald D. Cagle

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09/26/2006

EXAMINER

FORD, ALLISON M

ALCON

IP LEGAL, TB4-8

6201 SOUTH FREEWAY

FORT WORTH, TX 76134

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/705,441

Applicant(s)

CAGLE ET AL.

Examiner

Allison M. Ford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to a composition comprising a bicarbonate and an aqueous otologically acceptable vehicle, classified in class 424, subclass 686.
- II. Claims 15-57, drawn to a composition comprising a cerumenolytically acceptable enzyme and an aqueous otologically acceptable carrier, classified in class 424, subclass 94.1.
- III. Claims 58-60, drawn to a method of removing human cerumen using the composition of Group I, classified in class 424, subclass 686.
- IV. Claims 61-72, drawn to a method of removing human cerumen using the composition of Group II, classified in class 424, subclass 94.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II are directed to distinct compositions. Inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are each materially distinct, as the composition of Group I requires bicarbonate, which is not required by the composition of Group II; alternatively the composition of Group II requires a cerumenolytically acceptable enzyme, which is not required by the composition of Group I. Therefore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The inventions of Groups III and IV are directed to distinct processes. Inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed each require use of different compositions (the compositions of Group I and Group II, discussed above); because the compositions required for each of the methods are distinct, the methods are thus non-overlapping in design, operation and effect.

The inventions of Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Group I, a composition comprising bicarbonate and an otologically acceptable vehicle, can be used for materially distinct processes, for example, US Patent 3,970,594 to Claybaugh discloses an aqueous cleaning composition comprising a surfactant, a 'builder', and a mixture of polymeric material and polysaccharide, wherein the builder is a bicarbonate, and the polymeric material is polyvinyl alcohol (See Claybaugh, claims 1, 4, 7 and 10). Thus an aqueous composition comprising a bicarbonate, a surfactant, and polyvinyl alcohol (a demulcent) can alternatively be used to clean hard surfaces, a material distinct process from that of the Group III.

The inventions of Groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Group II, a composition comprising a cerumenolytically acceptable enzyme and an otologically acceptable vehicle, can be used for materially distinct processes, for example, US

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Patent 6,139,646 to Asgharian et al discloses use of a composition comprising methyl trypsin (an cerumenolytically acceptable enzyme) in borate buffer (an otologically acceptable vehicle) for cleaning contact lenses (See Asgharian et al, col. 5, ln 30-37). Thus an aqueous composition comprising a cerumenolytically acceptable enzyme and an otologically acceptable vehicle can alternatively be used to clean contact lenses, a materially distinct process from that of Group IV.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

The following elections of species are further required. **SIX (6) elections are required in total.**

1. Species of Demulcent:

Claims 1, 21 and 50 are generic to a plurality of distinct species of demulcents, the species are as follows: a) povidone; b) polyvinyl alcohol; c) glycerin; d) propylene glycol; e) polyethylene glycol; f) cellulose derivatives. Claims 4, 9, 25 and 26 recite one or more of the above species.

2. Species of Surfactant:

Claims 1, 22 and 51 are generic to a plurality of distinct species of surfactants, the species are as follows: g) polysorbates; h) 4-(1,1,3,3-tetramethylbutyl) phenol/poly(oxyethylene) polymers; l) poly(oxyethylene)-poly(oxypropylene) block copolymers; j) polyethylene glycol esters of fatty acids; k) polyoxypropylene ethers of higher alkanes (C12-C18). Claims 5, 10, 26 and 30 recite one or more of the above species.

3. Species of Preservative:

Claims 1, 23 and 52 are generic to a plurality of distinct species of preservatives, the species are as follows: l) poly[dimethylimino-2-butene-1,4-diyl]chloride-alpha-[4-tris(2-hydroxyethyl)ammonium]dichloride; m) benzalkonium halides; n) alexidine salts; o) chlorhexidine salts; p) hexamethylene biguanimides and their polymers; q) combination or mixture thereof (specific combination must be elected). Claims 6, 13, 27 and 31 recite one or more of the above species.

4. Species of Buffer:

Claims 3, 24 and 53 are generic to a plurality of distinct species of buffers, the species are as follows: r) citrate buffer and salts thereof; s) phosphate buffer and salts thereof; t) borate buffer and salts thereof; u) acetate buffer and salts thereof; v) Tris buffer and salts thereof; combinations thereof (specific combination must be elected). Claims 7, 13, 28, and 32 recite one or more of the above species.

5. Species of Cerumenolytically Acceptable Enzyme:

Claims 15, 41 and 61 are generic to a plurality of distinct species of enzymes, the species are as follows: w) lipases; x) pancreatin; y) trypsin (including methyl trypsin); z) subtilisin; aa) collagenase; bb) keratinase; cc) carboxypeptidase; dd) papain; ee) bromelain; ff) aminopeptidase; gg) elastase; hh) Aspergillo peptidase; ii) pronase E from *S. griseus*; jj) dispase from *Bacillus polymyxa*; kk) combinations of (y)-(kk) (specific combination must be elected); ll) amylases; mm) combinations thereof (specific combination must be elected). Claims 15-20, 33, 40, 43-48, 62-67 and 72 recite one or more of the above species.

6. Species of Enzyme Stabilizing Agent:

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Claims 34 and 54 are generic to a plurality of distinct species of enzyme stabilizing agents, the species are as follows: nn) monomeric polyols; oo) polymeric polyols; pp) calcium ions; qq) borate/boric acid compound. Claims 35, 36 and 55 recite one or more of the above species.

The species within each of the six groups above are independent or distinct because none of the species are automatically rendered obvious by the others in its group as they are not all art recognized equivalents. Additionally, the disclosure does not connect every species of each of the above described genres by design, structure, operation, or effect. See M.P.E.P. § 806.04(b). A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required. See M.P.E.P. § 808.01(a). In this case, considering enablement, utility, and description issues for each claimed species, as well as conducting a thorough search of the prior art for each and every combination embodied by the present claims, would pose a serious burden to the examiner.

The examiner wishes to point out for the record that an election of species requirement is for search purposes only and does not necessarily narrow the scope of patentable claims, since all nonelected species are rejoined at the time of allowance. See 37 C.F.R. § 1.146 and M.P.E.P. § 809.02(c) for a discussion of species election practice. In short, electing one species does not preclude consideration of the nonelected species later in the prosecution, *i.e.* at the time of allowance. The fact that all of the original claims were generic was the precise reason for the requirement for species election; in the interest of expedient processing of applications, the examiner concentrates on the patentability of the entire invention as it pertains to one species. Once the invention *per se* is claimed in an allowable manner, all disclosed species are rejoined to the claims.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai*, *In re Brouwer* and 34 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

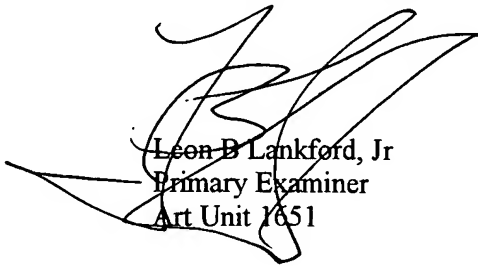
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B Lankford, Jr
Primary Examiner
Art Unit 1651